



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/229,751 01/14/99 TURNBOUGH

C

GLNNA HENDRICKS
PO BOX 2509
FAIRFAX VA 22031-2509

HM22/0130

EXAMINER

WESSENDORF, T

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

01/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/229,751

Applicant(s)

Turnbiugh

Examiner

T. Wessendorf

Group Art Unit

1627



☒ Responsive to communication(s) filed on 11/27/00

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-9, 11-14, and 16-22 is/are pending in the application

Of the above, claim(s) 1-9, 14, 16, 17, 19, and 20 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 11-13, 18, 21, and 22 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1627

Claims 11-13, 18 and 21-22 are pending in the instant application.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-13, 18 and 21-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed composition comprising of a peptide ligand and a sample suspected of containing spores is not supported in the as-filed specification. The original disclosure at e.g., page 15, lines 8-11, recites for a pharmaceutical composition of a peptide derived from a phage display library.

Art Unit: 1627

Claims 11-13, 18, 21-22 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The claimed composition which is supposed to be a pharmaceutical composition that contains the peptide ligand derived from phage display library capable of binding bacterial spores or organisms is critical or essential to the practice of the invention, but not included in the claim(s) and therefore is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Also, the disclosure describes what appears to be a modified biopanning method that identifies a peptide ligand from a library that binds specifically to the disclosed bacterial spores.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Art Unit: 1627

Claims 11-13, 18 and 21-22 are rejected under 35 U.S.C. 101 because the claimed composition is drawn to non-statutory subject matter.

The claimed composition drawn to a peptide ligand and a sample containing the recited bacterial species is a non-statutory subject matter since it is drawn to a composition that occurs in nature i.e., as a naturally occurring composition. The natural environment e.g., water or air pollutants which contains bacterial spores or organisms contain also other organic molecules such as peptides that binds to bacteria that forms a complex of bacteria-organic composition. The claims are clearly drawn to a composition of nature wherein the components have not been isolated or purified to identify the components present therein.

Claims 11-13, 18 and 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claim 21 is indefinite in the recitation of a sample suspected to contain spores. The claim fails to recite how a sample is suspected to contain the spores, especially in the absence of positive support in the specification. Also, the term

Art Unit: 1627

'particular' fails to ascertain the claimed invention with precision.

B). Claim 22 is indefinite as the term 'specificity' is a relative term, the basis or standard by which said term is determined is not clearly set forth. Furthermore, it is not clear whether said ligand is positively bound to a solid support as the term being fails to claim it with precision.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 10, 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ezzell et al (Jrnl. of Clinical Microbiology).

Ezzell discloses a composition comprising peptide ligand i.e., a monoclonal antibody that binds to Bacillus spores and a

Art Unit: 1627

sample suspected of containing said Bacillus spores. See particularly, page 223, abstract; page 226, col. 1 up to page 228, col. 1. The claimed composition is therefore fully met by the composition of Ezzell.

Claims 10-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Hutchens et al (5,719,060).

Hutchens discloses at e.g., col. 23, Example 3 up to col. 24, line 30 composition comprising of a peptide ligand linked to a polymeric solid support. The broadly claimed composition is therefore anticipated by the specific composition of Hutchens. The recitation of the functional limitation in a composition does not make the composition different as the components of the composition are the same.

Claims 10, 15, 18 are rejected under 35 U.S.C. 102(a) as being anticipated by either D' Mello et al (Virology) or applicant's disclosure of known art.

D'Mello discloses at e.g., page 320, cols. 1 and 2; page 322, cols. 1 and 2 composition comprising of a peptide ligand linked to a polymeric solid support. Applicant admits at e.g., page 2, lines 4-5 that "...the peptides are included in phage display peptide libraries that, are commercially available...." Furthermore, at page 4, second complete paragraph applicant admits that " phage display ligand screening was employed using a

Art Unit: 1627

statutory period for reply expire later than SIX MONTHS from the date of this final action.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1627.

Certain papers related to this application may be submitted to Art Unit 1627 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 O.G. 61 (November 16, 1993) and 1157 O.G. 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone numbers of the Group are (703)308-7924. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat Ph.D., can be reached on (703) 308-0570. Any inquiry of a general

Art Unit: 1627

commercially available combinatorial library of ..random peptide sequences.." See also page 5. The broadly claimed composition is therefore anticipated by the specific composition of D'Mello or the art cited by applicant. The recitation of the functional limitation in a composition does not make the composition different as the components of the composition are the same.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the

Art Unit: 1627

nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



T. Wessendorf
Patent Examiner
Art Unit 1627
1/29/01